

[~116H8467]

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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to refine the set of information sources for determining coverage of certain drugs and biologicals used in the treatment or management of a rare disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. MATSUI introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to refine the set of information sources for determining coverage of certain drugs and biologicals used in the treatment or management of a rare disease or condition, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Providing Realistic Op-
3 portunity to Equal and Comparable Treatment for Rare
4 Act” or the “PROTECT Rare Act”.

5 **SEC. 2. COVERAGE OF CERTAIN DRUGS USED IN TREAT-**
6 **MENT OR MANAGEMENT OF RARE DISEASE**
7 **OR CONDITION.**

8 (a) MEDICARE.—

9 (1) IN GENERAL.—Section 1861(t)(2) of the
10 Social Security Act (42 U.S.C. 1395x(t)(2)) is
11 amended—

12 (A) in subparagraph (A), by inserting after
13 “regimen” the following: “, or in the treatment
14 or management of a disease or condition affect-
15 ing 200,000 or fewer individuals in the United
16 States,”; and

17 (B) in subparagraph (B)(ii)—

18 (i) in subclause (I), by striking “, or”
19 at the end and inserting a semicolon;

20 (ii) in subclause (II), by striking the
21 period at the end and inserting “; or”; and

22 (iii) by adding at the end the fol-
23 lowing new subclause:

24 “(III) in the case of a drug that
25 is used in the treatment or manage-
26 ment of a disease or condition affect-

1 ing 200,000 or fewer individuals in
2 the United States, such use is sup-
3 ported by peer-reviewed medical lit-
4 erature, including clinical guidelines,
5 and is not reviewed unfavorably in the
6 compendia described in section
7 1927(g)(1)(B)(i), or listed as a con-
8 traindication in the FDA-approved la-
9 beling.”.

10 (2) MEDICALLY ACCEPTED USES OF COVERED
11 PART D DRUGS IN TREATING RARE CONDITIONS.—
12 Section 1860D–2(e)(4)(A) of the Social Security Act
13 (42 U.S.C. 1395w–102(e)(4)(A)) is amended—

14 (A) in clause (i)(II), by striking “and”;
15 (B) by redesignating clause (ii) as clause
16 (iii); and
17 (C) by inserting after clause (i)(II) the fol-
18 lowing new clause:

19 “(ii) in the case of a covered part D
20 drug used in the treatment or management
21 of a disease or condition affecting 200,000
22 or fewer individuals in the United States,
23 in section 1861(t)(2)(B); and”.

24 (3) EFFECTIVE DATE.—The amendments made
25 by this subsection apply with respect to items and

1 services furnished on or after the date that is 30
2 days after the date of the enactment of this Act.

3 (b) MEDICAID.—

4 (1) IN GENERAL.—Section 1927(k)(6) of the
5 Social Security Act (42 U.S.C. 1396r–8(k)(6)) is
6 amended to read as follows:

7 “(6) MEDICALLY ACCEPTED INDICATION.—The
8 term ‘medically accepted indication’ means any use
9 for a covered drug—

10 “(A) which is approved under the Federal
11 Food, Drug, and Cosmetic Act;

12 “(B) which is supported by one or more ci-
13 tations included or approved for inclusion in
14 any of the compendia described in subsection
15 (g)(1)(B)(i); or

16 “(C) in the case of a drug used to treat or
17 manage a disease or condition affecting
18 200,000 or fewer individuals in the United
19 States—

20 “(i) the use of such drug is supported
21 by peer-reviewed medical literature, includ-
22 ing clinical guidelines; and

23 “(ii) is not reviewed unfavorably in
24 the compendia described in subsection

1 (g)(1)(B)(i), or listed as a contraindication
2 in the FDA-approved labeling.”.

3 (2) CONFORMING AMENDMENT.—Section
4 1927(d)(4)(C) of the Social Security Act (42 U.S.C.
5 1396r–8(d)(4)(C)) is amended by striking “com-
6 pendia” and inserting “sources”.

7 (3) EFFECTIVE DATE.—The amendments made
8 by this subsection apply with respect to covered out-
9 patient drugs furnished on or after the date that is
10 30 days after the date of the enactment of this Act.

11 (c) PRIVATE HEALTH INSURANCE.—

12 (1) IN GENERAL.—Subpart II of part A of title
13 XXVII of the Public Health Service Act (42 U.S.C.
14 300gg–19.) is amended by adding at the end the fol-
15 lowing new section:

16 **“SEC. 2730. EXPEDITED PROCESSES FOR REVIEW ASSOCI-**
17 **ATED WITH CERTAIN DRUGS USED IN TREAT-**
18 **MENT OR MANAGEMENT OF A RARE DISEASE**
19 **OR CONDITION.**

20 “A group health plan or a health insurance issuer of-
21 fering group or individual health insurance coverage shall
22 provide a mechanism for expedited formulary exception,
23 reconsideration, and appeal of any denial of coverage for
24 a drug or biological—

1 “(1) approved by the Food and Drug Adminis-
2 tration;

3 “(2) for which the use is related to treatment
4 or management of a disease or condition affecting
5 200,000 or fewer individuals in the United States;
6 and

7 “(3) the use of which is supported by the FDA-
8 approved label or peer-reviewed literature, including
9 clinical guidelines, and that is not reviewed unfavor-
10 ably in the compendia described in section
11 1927(g)(1)(B)(i)) of the Social Security Act or listed
12 as a contraindication in the FDA-approved label-
13 ing.”.

14 (2) EFFECTIVE DATE.—The amendment made
15 by this subsection applies with respect to plan years
16 beginning on or after the date that is 30 days after
17 the date of the enactment of this Act.